

FOOD AND DRUG ADMINISTRATION
Center for Tobacco Products (CTP)

Tobacco Products Scientific Advisory Committee (TPSAC)

Center for Tobacco Products
9200 Corporate Blvd.
Rockville, MD 20850

March 1, 2012

These summary minutes for the March 1, 2012 meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration were approved on March 5, 2012.

I certify that I attended the March 1, 2012 meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.

_____/s/_____
Caryn Cohen, M.S.
Designated Federal Official, TPSAC

_____/s/_____
Jonathan Samet, M.D., M.S.
Committee Chair, TPSAC

Meeting of the Tobacco Products Scientific Advisory Committee March 1, 2012

The Tobacco Products Scientific Advisory Committee (TPSAC) of the Food and Drug Administration, Center for Tobacco Products (CTP) met on March 1, 2012 at the Center for Tobacco Products, 9200 Corporate Blvd., Rockville, Maryland, 20850. The meeting was originally scheduled for March 1-2, 2012, but the Committee completed their agenda on March 1, 2012. Prior to the meeting, committee members and invited guests were provided copies of background material from the FDA and submissions from the public. The meeting was called to order by Jonathan Samet, M.D., M.S. (Committee Chair); the conflict of interest statement was read into the record by Caryn Cohen, M.S. (Designated Federal Official). There were approximately 80 persons in attendance. There were 4 speakers for the Open Public Hearing session on March 1, 2012. The meeting was webcast; a link to the webcast was provided on the CTP website in the Advisory Committee section.

Agenda: As part of the TPSAC's required report to the Secretary of Health and Human Services, the committee completed their discussion of issues related to the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children. Discussion included such topics as the composition and characteristics of dissolvable tobacco products, product use, potential health effects, and marketing.

The meeting was held on March 1, from 1:00 p.m. to 7:00 p.m. and was open to the public. The previously scheduled closed session, to permit discussion and review of trade secret and confidential commercial information (5 U.S.C. 552b(c)(4)), was canceled.

Attendance:

Tobacco Products Scientific Advisory Committee (Voting):

Jonathan Samet, M.D., M.S. (Committee Chair)

Neal Benowitz, M.D.

Mark Clanton, M.D., M.P.H.

Dorothy Hatsukami, Ph.D.

Thomas Eissenberg, Ph.D.

Industry Representative Members (Non-voting):

Luby Arnold Hamm (Tobacco Growers Representative – via Tele-conference)

Daniel Heck, Ph.D, D.A.B.T. (Tobacco Manufacturing Industry Representative)

John Lauterbach, Ph.D., D.A.B.T. (Small Business Tobacco Manufacturing Industry Representative)

Ex Officio Members (Non-Voting):

Mirjana Djordjevic, Ph.D.

Sandrine Pirard, M.D., Ph.D., M.P.H.

Timothy McAfee, Ph.D., M.P.H.

Temporary Voting Members:

Robert L. Balster, Ph.D.

Fred Pampel, Ph.D.

Consultants (Non-Voting):

Bruce Simons-Morton, Ed.D., M.P.H. (Afternoon of March 1 and March 2 only)

Sherry Emery, M.B.A., Ph.D. (Via tele-conference March 1 only)

Ellen Peters, Ph.D.

FDA Participants (Non-Voting):

David Ashley, Ph.D.

Cathy Backinger, Ph.D.

Sarah E. Evans, Ph.D.

Designated Federal Official:

Caryn Cohen, M.S.

The agenda was as follows:

March 1 – open session

Call to Order	Jonathan Samet, M.D., M.S. Chair, TPSAC
Conflict of Interest Statement	Caryn Cohen, M.S. Designated Federal Official, FDA/CTP
Introduction of Committee Members	Jonathan Samet, M.D., M.S. Chair, TPSAC
Opening Remarks	Sarah E. Evans, Ph.D. Social Scientist Office of Science, FDA/CTP
Open Public Hearing	Elaine Keller - The Consumer Advocates for Smokefree Alternatives Association Bill Godsall - Smokefree Pennsylvania Michael W. Ogden, Ph.D. - R. J. Reynolds Tobacco Company James E. Dillard, III - Altria Client Services

Committee Discussion

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**Questions to the Committee:**

1. Regarding the Summary of the TPSAC consideration of dissolvable tobacco products, please be prepared to discuss in detail at the meeting what changes should be made to any part of the document.
  - a. In particular, do you have any disagreements or concerns regarding the key findings from the evidence review? What changes would you make to this assessment of the available evidence?
  - b. In particular, do you have any disagreements or concerns regarding the recommendations for further information gathering, surveillance and research? What changes should be made to these recommendations for further information gathering and study?
2. The TPSAC report on dissolvable tobacco products will include the above referenced Summary document as well as the background materials, transcripts, presentations, and minutes from the three TPSAC meetings on dissolvable tobacco products. Would you like to provide any clarification for or dispute any information provided to the committee or resulting from the committee process (e.g. meeting transcripts) that will become part of the committee report?

*The Committee reviewed the Draft summary of the Report in detail and, with extensive discussion, completed the editing of the document. Questions 1 and 2 were addressed by the Committee as part of the editing and review of the Draft Summary. Please see the transcript for details on the discussion and changes to the Summary.*

3. Voting question:  
Do you agree with the report, which consists of a summary from the Committee, as well as background materials, transcripts, presentations, and minutes from all TPSAC meetings on dissolvable tobacco products?

*Yes - 7*

*No - 0*

*Abstain - 0*

*All seven voting Members stated that they agreed with the Report. It was also mentioned that the Summary fairly summarizes the process and the current state of understanding of the dissolvable tobacco products. The difficulties of reaching a decision with the limited information available were acknowledged. The Chair thanked the industry Representatives for their participation and input.*

The meeting adjourned at 7:00 p.m.

**Please see the *verbatim* transcript for details of the discussion.**